

Appl. No. : 09/403,625
Filed : February 7, 2000

within the scope of the claim to enable a skilled artisan to recognize that Applicants were in possession of the claimed invention.

Claim 6 is directed towards an "isolated proteinic or glycoproteinic inhibitor of xylanase obtainable from a plant selected from the group consisting of cereals, cereal grains from wheat, cereal flours from wheat, durum wheat, rye, triticale, barley, sorghum, oats, maize and rice". In contrast to the Examiner's assertion that the specification describes only a single species within the claimed genus, in fact the specification describes the inhibition of xylanases by extracts from wheat, rye and barley (See page 20, line 18-page 21, line 10 and Figure 2). Accordingly, Applicants have described several species within the claimed genus. For the foregoing reasons, Applicants maintain that the specification describes a sufficient number of species to enable the skilled artisan to recognize that Applicants were in possession of the claimed invention.

The present invention is also directed towards an "isolated proteinic or glycoproteinic inhibitor comprising an amino acid sequence at least 70% homologous to SEQ ID NO:1 or SEQ ID NO:2," as recited in amended Claim 8.

The xylanase inhibitor of Claim 8 is described in the specification on page 5, line 23 to page 6, line 10 as a water-soluble alkaline proteinaceous species having a pI of greater than about 7.0 with a molecular weight of about 40-43 kDa (determined by SDS-PAGE). The N-terminal sequence(s) of the two subunits of the inhibitor are listed on page 6, lines 1-9 as SEQ ID NO:1 (14 amino acids) and SEQ ID NO:2 (17 amino acids). As discussed below, even in situations where only a single species is disclosed in the specification, the P.T.O. regularly finds that the disclosure of that species satisfies the written description and enablement requirements with respect to claims reciting sequences homologous to the disclosed species.

III. Rejections Based on the Assertion that the Specification Does Not Satisfy the Enablement Requirement

The Examiner asserts that the specification does not enable one skilled in the art to make and use the claimed invention and that undue experimentation would be required to obtain the claimed invention.

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As recited in amended Claim 6, the xylanase inhibitor is "...obtainable from a plant selected from the group consisting of cereals, grains from wheat, cereal flours from wheat, durum wheat, rye, triticale, barley, sorghum, oats, maize and rice." As discussed above, Applicants have in fact described the preparation of extracts from several species which contain xylanase inhibitors. Applicants have also described assays for identifying xylanase inhibitors. The extension of Applicants disclosure to additional species merely involves routine experimentation. For example, those skilled in the art may readily prepare extracts using the methodology described in the specification, assay the extracts for xylanase activity as described in the specification, purify the xylanases as described in the specification and sequence the purified xylanases as described in the specification. Alternatively, those skilled in the art may obtain additional xylanase inhibitors by using standard hybridization or PCR technology to isolate nucleic acids homologous to the N-terminal sequences which Applicants have provided in the specification as SEQ ID NO:1 and SEQ ID NO:2. Thus, given Applicants disclosure, one of skill in the art may practice the claimed invention using routine methodology. The court of Appeals for the Federal Circuit has determined that the implementation of routine screening techniques, even if labor-intensive, does not rise to the level of undue experimentation. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

Furthermore, with respect to the homologous polypeptides recited in Claim 8 and the claims the dependent therefrom, Applicants note that the U.S.P.T.O. routinely finds that the disclosure of a single species satisfies the written description and enablement requirements with respect to claims to homologous sequences. Applicant notes that a search of the P.T.O. database for claims containing the term "homology" in patents issued between 1996 and the present time yielded 378 patents satisfying the search criteria. A few representative examples of recently issued patents containing claims to homologous sequences include Claim 2 of U.S. Patent Number 6,267,956, Claim 6 of U.S. Patent Number 6,265,201, Claim 7 of U.S. Patent Number 6,277,612, copies of which are attached hereto as Exhibits A-C. Accordingly, Applicant maintains that Claim 8 and the claims dependent therefrom meet all the statutory requirements.

Appl. No. : 09/403,625
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In view of above remarks, Applicants respectfully request withdrawal of the rejection to Claims 6 to 13 for failing to meet the written description and enablement requirements.

IV. Conclusion

Claims 6-13 have been amended to provide that the claimed inhibitors are isolated. The changes made to the claims by the current amendment, including insertions and [deletions], are shown on an attached sheet entitled **VERSION WITH MARKINGS TO SHOW CHANGES MADE**, which follows the signature page of this amendment. No new matter has been added herewith.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is fully in condition for allowance. Should there be any questions concerning this application, the Examiner is invited to contact the undersigned attorney at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Appl. No. : 09/403,625
Filed : February 7, 2000

VERSION WITH MARKINGS TO SHOW CHANGES MADE

6. **(Amended three times)** An isolated proteinic or glycoproteinic inhibitor of xylanase obtainable from a plant selected from the group consisting of cereals, cereal grains from wheat, cereal flours from wheat, durum wheat, rye, triticale, barley, sorghum, oats, maize and rice.

7. **(Twice amended)** The isolated inhibitor of claim 6, wherein said inhibitor is water-soluble.

8. **(Twice amended)** [The]An isolated proteinic or glycoproteinic inhibitor [of claim 7]of xylanase comprising an amino acid sequence at least 70% homologous to SEQ ID NO:1 or SEQ ID NO:2.

9. **(Twice amended)** The isolated inhibitor of claim 8, wherein the amino acid sequence is the N-terminal amino acid sequence of the protein or glycoprotein.

10. **(Twice amended)** The isolated inhibitor of claim 8 comprising an amino acid sequence at least 85% homologous to SEQ ID NO:1 or SEQ ID NO:2.

11. **(Twice amended)** The isolated inhibitor of claim 10, wherein the amino acid sequence is the N-terminal amino acid sequence of the protein or glycoprotein.

12. **(Twice Amended)** The isolated inhibitor of claim 7, comprising SEQ ID NO:1 or SEQ ID NO:2.

13. **(Twice amended)** The isolated inhibitor of claim 12, wherein SEQ ID NO:1 or SEQ ID NO:2 is the N-terminal amino acid sequence of the protein or glycoprotein.